***In re National Prescription Opiate Litigation*: MDL 2804**
Summary Sheet of Concise Issues Raised

Opposition Name: Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Preemption Summary Judgment Motions (Dkt. #s 1754, 1760, 1772)

Opposing Parties: Plaintiffs Summit County and Cuyahoga County

Issue 1: Are Plaintiffs' state law claims preempted?

Answer: No. Plaintiffs assert various state law claims based on the Defendants' fraudulent and misleading marketing of opioid medications, and the failure of Defendants to comply with state law duties in connection with their sale and distribution of dangerous controlled substances. Plaintiffs' claims do not conflict with the Controlled Substances Act (CSA), which specifically contemplates the states' traditional enforcement of tort law to supplement the federal enforcement scheme.

The Supreme Court has long "regarded state law as a complimentary form of drug regulation" and "state law offers an additional, and important, layer of consumer protection that complements [federal] regulation." *Wyeth v. Levine*, 555 U.S. 555, 579-80 (2009). Even though some of the Defendants' misconduct violated the CSA, the CSA is not the only source of the Defendants' legal duty. Nor do Plaintiffs' claims run afoul of *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), because their claims do not exist solely by virtue of federal law, but are predicated on violations of state common and statutory law and regulations that are consistent with and parallel to federal obligations.

Plaintiffs' claims are also based on the Defendants' tortious conduct in failing to stop shipments of suspicious opioid orders. Even if the Defendants' conduct *also* violates obligations under the CSA, that does not preclude Plaintiffs from asserting their state law claims.

Plaintiffs do not challenge the FDA-approved labeling of any of the Manufacturers' products, but rather their false and misleading promotion of those drugs. Federal law did not *require* the Manufacturers to promote their products—let alone to promote them misleadingly, through falsehoods and omissions. Nor have the Manufacturers shown that Plaintiffs' fraudulent marketing claims conflict in any way with the regulatory actions taken by the FDA.

Issue 2: Are Plaintiffs' RICO claims precluded?

Answer: No. Because Plaintiffs' state law claims are not preempted, their RICO claims are likewise not precluded.

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Reply Date: August 16, 2019

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION *This document relates to:* Track One Cases	MDL 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

PLAINTIFFS' CONSOLIDATED MEMORANDUM IN OPPOSITION TO DEFENDANTS' PREEMPTION SUMMARY JUDGMENT MOTIONS (Dkt. #s 1754, 1760, 1772)

July 31, 2019

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INTRODUCTION

Three groups of defendants filed summary judgment motions asserting that Plaintiffs' claims are preempted: (1) Motion for Summary Judgment on Preemption by Pharmacy Defendants, ABDC, Cardinal, and McKesson (Doc. 1772); (2) The Non-RICO Small Distributors' Motion for Partial Summary Judgment on Plaintiffs' "Failure to Report" and "Fraud on the DEA" Claims (Doc. 1754); and (3) Manufacturer Defendants' Motion for Summary Judgment that Plaintiffs' State-Law Claims are Preempted and their Federal Claims are Precluded (Doc. 1760). These motions involve related, overlapping and, in some instances, conflicting issues.

The defendants' motions largely seek to relitigate preemption issues that have already been decided in connection with their motions to dismiss, and nothing has changed since that time that would compel a different result. Moreover, the defendants' motions all rest on mischaracterizations of Plaintiffs' claims. Plaintiffs assert common law claims (and certain state and federal statutory claims) that do not conflict with federal law and are not preempted by it. Consequently, Plaintiffs file this consolidated response in opposition to all three motions.

I. PLAINTIFFS' RESPONSE TO THE PHARMACY AND LARGE DISTRIBUTOR DEFENDANTS' MOTION FOR SUMMARY JUDGMENT REGARDING PREEMPTION (Dkt. 1772)

The sole preemption argument offered by the Pharmacy and Distributor Defendants is that "imposition of state tort liability would stand as an obstacle to DEA's ability to regulate and enforce" the Controlled Substances Act (CSA). Doc. 1772-05, p. 1. The argument lacks merit, as it relies on a mischaracterization of the CSA, the controlling case law, and Plaintiffs' claims. This Court and other courts have previously rejected this type of obstacle-preemption argument. *See* Report & Recommendation, Doc. 1499, PageID #: 43045-43059; Opinion & Order, Doc. 1680 (adopting R&R with respect to preemption); Report & Recommendation, Doc. 1025, PageID #: 24854-24860; Opinion & Order, Doc. 1203 (adopting the R&R with respect to preemption). *See also In re Opioid*

Litigation, 2018 WL 3115102 (N.Y. Sup. Ct., June 18, 2018) (rejecting similar preemption arguments). There is nothing in the Pharmacy and Distributor Defendants' instant motion that justifies a different conclusion. Not surprisingly, they fail to cite any decision in which any court has agreed with their preemption argument.

The Pharmacy and Distributor Defendants argue that the CSA strikes a balance between making the distribution of controlled substances "too restricted" and "too free" and that, *ipso facto*, the imposition of state tort liability would "stand as an obstacle to the accomplishment of the full purposes and objectives of Congress in enacting the CSA and of DEA in regulating under it." Doc. 1772-5, pp. 1, 3. But they are wrong; Plaintiffs' claims do not interfere with the CSA in any way. Plaintiffs merely seek to hold the Pharmacy and Distributor Defendants responsible for conduct that violates state law *as well as* the CSA. Rather than interfere with the CSA, Plaintiffs' claims are of the type specifically contemplated by it: the CSA welcomes the states' traditional enforcement of tort law to supplement the federal enforcement scheme. Congress essentially said as much when it included a provision in the CSA titled "Application of State Law" and stated therein:

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

21 U.S.C. § 903. Congress clearly embraces the states' continued exercise of their traditional role in the enforcement of tort law, even in circumstances where liability might be premised in part on the violation of the CSA—so long as there is not "a positive conflict" between state law and the CSA.

There is additional evidence that the CSA contemplates—and encourages—states to play a role in regulating the health and safety of their citizens when it comes to controlled substances. This evidence comes from the DEA policy statement quoted throughout the Pharmacy and Distributor Defendants' brief: "Dispensing Controlled Substances for the Treatment of Pain," 71 Fed. Reg.

52716-01, 2006 WL 2540907 (Sep. 6, 2006). The Pharmacy and Distributor Defendants cite this policy statement to try to demonstrate that any imposition of liability under state law would "conflict" with the goals of the CSA and of DEA's responsibility to enforce it. Actually, the policy statement demonstrates the opposite, as it urges states to continue their historic role of regulating the flow of dangerous medications into their communities:

> DEA's role under the CSA is to ensure that controlled substances are prescribed, administered, and dispensed only for legitimate medical purposes by DEA-registered practitioners acting in the usual course of professional practice and otherwise in accordance with the CSA and DEA regulations. Each State also has its own laws (administered by State agencies) requiring that a prescription for a controlled substance be issued only for a legitimate medical purpose by State-licensed practitioners acting in the usual course of professional practice.
>
> There is nothing new in this arrangement of responsibilities between the Federal and State governments. For more than 90 years (starting with the Harrison Narcotic Act of 1914, which was superseded by the CSA in 1970) Federal law has placed certain restrictions on the medical use of federally controlled substances while, at the same time, the States have regulated the practice of medicine generally. In this respect, there has long been a certain amount of overlap between the Federal and State oversight of controlled substances. … Accordingly, it has been the case for more than 70 years that a practitioner who dispenses controlled substances for other than a legitimate medical purpose, or outside the usual course of professional practice, is subject to legal liability under both State and Federal law.

71 Fed. Reg. 52716-01, 52717.[1]

As the Supreme Court observed when it rejected an obstacle-preemption argument similar to the one made by the Pharmacy and Distributor Defendants (albeit in the context of the Federal Food, Drug, and Cosmetic Act (FDCA)), the FDA, with "limited resources to monitor the 11,000 drugs on the market," "regarded state law as a complementary form of drug regulation." *Wyeth v. Levine*, 555 U.S. 555, 579 (2009). The Supreme Court noted that "the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Id.* at 580. The Supreme Court explained:

[1] The policy statement is limited to the role of prescribers and does not discuss the role of distributors and pharmacies. But it nevertheless makes clear that states continue to play a role in the regulation of controlled substances.

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70–year history. But despite its 1976 enactment of an express pre-emption provision for medical devices…Congress has not enacted such a provision for prescription drugs.…Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.

Id. at 574–75. The same can be said of the CSA and DEA—and in fact DEA said as much in the policy statement referenced above.[2]

Some of the Pharmacy and Distributor Defendants' misconduct violated the CSA, to be sure, but the CSA is not the source—or at least not the only source—of the legal duty. This is no different from any tort case in which the defendant's wrongful conduct happens to have violated a federal statute or regulation. Although the violation may provide evidence of the defendant's breach, the duty of care itself derives principally from state tort law. In Ohio, for instance, the violation of a federal OSHA regulation is ***evidence*** of negligence, even though the source of the legal duty remains rooted in Ohio tort law. *Reising v. Broshco Fabricated Prods.*, 2006-Ohio-4449, ¶ 58 (Ct. App.) (noting that an OSHA violation "may be admissible as evidence of negligence"); *Chambers v. St. Mary's Sch.*, 1998-Ohio-184, 82 Ohio St. 3d 563, 563, 697 N.E.2d 198 ("The violation of an administrative rule does not constitute negligence *per se*; however, such a violation may be admissible as evidence of negligence.").

[2] Justice Thomas's concurring opinion in *Wyeth* went even further than the majority, and questioned the continuing vitality of the Supreme Court's obstacle preemption jurisprudence: "I have become increasingly reluctant to expand federal statutes beyond their terms through doctrines of implied pre-emption. My review of this Court's broad implied pre-emption precedents, particularly its 'purposes and objectives' pre-emption jurisprudence, has increased my concerns that implied pre-emption doctrines have not always been constitutionally applied. Under the vague and potentially boundless doctrine of 'purposes and objectives' pre-emption, *Geier v. American Honda Motor Co.*, 529 U.S. 861, 907, 120 S. Ct. 1913, 146 L.Ed.2d 914 (2000) (STEVENS, J., dissenting), for example, the Court has pre-empted state law based on its interpretation of broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not contained within the text of federal law." *Wyeth*, 555 U.S. at 587 (Thomas, J., concurring) (most citations and quotation marks omitted). Justice Thomas's skepticism is rooted in the fundamental federalist system the Framers adopted, which puts a premium on "a system of dual sovereignty between the State and the Federal Government" because it provides "a double security to the rights of the people" and recognizes the states "will be more sensitive" than the federal government "to the diverse needs of a heterogeneous society." *Id.* at 584.

Indeed, the U.S. Supreme Court has expressly approved the imposition of state tort liability even where the alleged wrongful conduct might also violate federal law. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) ("Nothing in [21 U.S.C] § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."). *See also Loreto v. Procter & Gamble Co.*, 515 F. App'x 576, 579–80 (6th Cir. 2013); *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 94–95 (2d Cir. 2006), *aff'd sub nom. Warner-Lambert Co., LLC v. Kent*, 552 U.S. 440 (2008). As the Supreme Court noted in *Lohr*,

> Congress does not cavalierly pre-empt state-law causes of action. In all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.

Id. at 485 (internal citations and quotation marks omitted). This approach "is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Id.*[3]

As this Court noted when it rejected a similar argument made by the Manufacturer Defendants, "Plaintiffs do not seek to enforce the provisions of the FDCA, instead they allege that Defendants fraudulently and misleadingly promoted their opioids. These allegations are of the type that would traditionally be brought as state law claims and, therefore, are not preempted." Report & Recommendation, Doc. 1025, PageID # 24860. *See also* Opinion & Order, Doc. 1203, PageID # 29021 (adopting the R&R with respect to preemption). The Court likewise explained: "Plaintiffs here seek to enforce an alleged state law duty to, for example, monitor the sales of drugs with due care—a

[3] Defendants claim their argument is supported by *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000), but *Geier* has nothing to do with this case. That case addressed the preemptive effect of a federal regulation related to the use of passive restraints in passenger vehicles. The Department of Transportation promulgated a regulation that "required auto manufacturers to equip some but not all of their 1987 vehicles with passive restraints." *Id.* at 864-65. The question before the Court was whether a state-law claim predicated on the failure of a manufacturer to pick a specific type of passive restraint (an air bag) was preempted. The Court said yes because the federal agency specifically decided that it wanted auto manufacturers to try a variety of different passive restraint systems. To allow a manufacturer to be held liable under state law for failing to install air bags in all their cars (rather than trying other passive restraint systems) would have "presented an obstacle to the variety and mix of devices that the federal regulation sought to phase in gradually." *Id.* at 881. No such issue or obstacle exists in this case.

claim that is not inconsistent with the purposes of the FDCA, and thus not preempted." Report & Recommendation, Doc. 1025, PageID # 24860. *See also* Opinion & Order, Doc. 1203, PageID # 29021 (adopting the R&R with respect to preemption). The same logic applies to the claims against the Pharmacy and Distributor Defendants.

Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 352-53 (2001), is the key case upon which the Pharmacy and Distributor Defendants rely to support their preemption argument. However, *Buckman* was a very narrow holding based on a unique set of facts and law which are simply not present in this case.

Buckman held that state tort claims may be preempted where the state tort claim "exists solely by virtue of" the federal law in question and does not "rely on traditional state tort law." The plaintiffs in *Buckman* asserted state-law claims based on injuries they sustained from the use of orthopedic bone screws. *Id.* at 343. They sued a consulting company that assisted the screws' manufacturer in navigating the federal regulatory process for approval of the screws. *Id.* The plaintiffs claimed the consulting company made fraudulent representations to the FDA in the course of obtaining approval to market the screws and that, but for the fraudulent representations, the FDA never would have approved the screws and, therefore, the plaintiffs never would have been injured. *Id.* The Supreme Court held that the state-law claims were preempted because the fraud claims "exist solely by virtue of the" the federal law that requires disclosure of information to the FDA during the approval process and thereby seek to police fraud against a federal agency. *Id.* at 347-348, 352-353.

Unlike the claims in *Buckman*, Plaintiffs' state-law claims against the Pharmacy and Distributor Defendants do not exist solely by virtue of federal law. Instead, Plaintiffs' claims against the Pharmacy and Distributor Defendants are based on their failure to maintain effective controls and to investigate, report, and take steps to halt orders they knew, or should have known, were suspicious. *See, e.g.*, Cuyahoga County's Third Amended Complaint, Doc. 1631, PageID #: 45791-45838. These claims

are predicated on the Pharmacy and Distributor Defendants' common-law duty to "exercise reasonable care in delivering dangerous narcotic substances." *Id.*, ¶ 486. That common-law duty imposed on the Pharmacy and Distributor Defendants the obligation to "set up a system to prevent diversion, including excessive volume and other suspicious orders," to report suspicious orders to relevant enforcement authorities, and to stop shipment of suspicious orders. *Id.*, ¶ 496. The Pharmacy and Distributor Defendants violated that duty when they "[chose] not to effectively monitor for suspicious orders," "[chose] not to investigate suspicious orders," and [chose] not to stop or suspend shipments of suspicious orders" "despite their actual knowledge of drug diversion rings." *Id.*, ¶¶ 1089, 548.

The report of Dr. Seth B. Whitelaw, a leading expert in corporate compliance programs within the pharmaceutical industry, confirms that the legal claims against the Pharmacy and Distributor Defendants are based on violations of numerous relevant standards, and that state law, including both statutes and regulations, are one source of the governing standards for effective compliance programs. Report of Seth B. Whitelaw, Dkt. #2000-26 at 6. The bulk of Dr. Whitelaw's report discusses at length the ways in which the Pharmacy and Distributor Defendant violated these standards. *Id.* at 44-238.

In short, Plaintiffs' state-law claims against the Pharmacy and Distributor Defendants are based upon a state-law duty of care and fit squarely within the traditional role states have played in regulating, through their tort regimes, matters of health and safety. The claims do not "stand as an obstacle to the accomplishment of the full purposes and objectives of Congress in enacting the CSA and of DEA in regulating under it." Doc. 1772-5, p. 1. Rather, they seek to enforce legal duties that parallel Defendants' responsibilities under the CSA. Because the Plaintiffs' claims would exist even in the absence of the CSA, they are not preempted. *Loreto*, 515 F. App'x at 579–80 (6th Cir. 2013) (rejecting, under *Buckman*, obstacle preemption where the wrongful conduct at issue "would give rise to liability under state law even if" the federal law "had never been enacted"). *See also Desiano*, 467 F.3d

at 95 ("In *Buckman,* there were no freestanding allegations of wrongdoing apart from the defendant's purported failure to comply with FDA disclosure requirements. And *Buckman* explicitly distinguished *Medtronic* on this ground.").[4]

II. PLAINTIFFS' RESPONSE TO THE NON-RICO SMALL DISTRIBUTORS' MOTION FOR PARTIAL SUMMARY JUDGMENT ON PLAINTIFFS' "FAILURE TO REPORT" AND "FRAUD ON THE DEA" CLAIMS (Dkt. 1754)

The Small Distributors argue three points: (1) Ohio does not recognize a claim for fraud on a federal agency (and even if it did such a claim would be preempted under *Buckman*); (2) the Controlled Substances Act does not provide a private right of action or a private remedy; and (3) Plaintiffs' claims are impliedly preempted under *Buckman*. But the Small Distributors' arguments – like the other defendants' arguments – are based on a fundamental mischaracterization of Plaintiffs' claims and the controlling law.

Plaintiffs' claims against the Small Distributors are not predicated on an allegation that they defrauded the DEA. Rather, those claims are based on the Small Distributors' tortious conduct in failing to stop shipments of suspicious orders. As discussed in Section I above, the Small Distributors' duties (like the Pharmacy and Distributor Defendants' duties) arose by virtue of Ohio common and statutory law, and even if the Small Distributors' conduct *also* violates obligations under the CSA, that does not preclude Plaintiffs from asserting their state law claims. As Magistrate Judge Ruiz noted, Plaintiffs' claims are based on common law duties "to use due care in selling their dangerous products

[4] At one point in their brief, the Pharmacy and Distributor Defendants stretch their argument to an absurd degree by claiming that Plaintiffs' causes of action are preempted regardless of whether they seek to impose liability for the distribution of opioids in violation of or "in compliance with the CSA." Doc. 1772-5, pp. 5-6. Thus, according to these Defendants, there could never be any state tort liability related to the distribution of opioids because both the violation of and the compliance with the CSA "would prevent DEA from fulfilling its mandate—in regulating under and enforcing the CSA—to implement the balance between the risk of diversion and the need to ensure that the American people have access to necessary drugs." *Id.*, p. 7. This is a thinly disguised argument for "field preemption." But field preemption is limited to those rare instances where Congress has regulated a field so pervasively that it "left no room for the States to supplement it." *Arizona v. United States*, 567 U.S. 387, 401 (2012). Here, Congress has expressly disavowed field preemption under the CSA. 21 U.S.C. § 903.

and that they are liable for failing to use such care." Report & Recommendation, Doc. 1025, PageID # 24858; Opinion & Order, Doc. 1203, PageID # 29021 (adopting the R&R with respect to preemption).

Likewise, the Small Distributors' argument that Plaintiffs are attempting to assert a private right of action to enforce the CSA is based on a mischaracterization both of Plaintiffs' claims and the controlling law. As discussed in Section I above, Congress clearly intended for states to play a complementary enforcement role in the context of the CSA through the use of tort law, unless there is a "positive conflict" between the CSA and state law "so that the two cannot consistently stand together." *See* 21 U.S.C. § 903. Since there is no conflict in Plaintiffs' asserting state law claims that parallel the CSA, Plaintiffs' claims are not preempted.

The Small Distributors' final argument is that Plaintiffs' claims are preempted under *Buckman*. For the reasons discussed in Section I above, *Buckman* is inapplicable and does not support a finding of preemption in this case.

III. PLAINTIFFS' RESPONSE TO THE MANUFACTURER DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON PREEMPTION (Dkt. 1760)

The Manufacturer Defendants once again attempt to argue that all of the Plaintiffs' state law claims are preempted by federal law. As in their motions to dismiss (and as the Pharmacy/Distributor and Small Distributors did in their preemption motions), the Manufacturers continue either to misunderstand Plaintiffs' claims, or seek to mislead the Court about those claims. The Manufacturers assert that Plaintiffs' claims are preempted because Plaintiffs challenge the safety and efficacy of opioid medications, and because the labeling changes the Manufacturers say Plaintiffs want would be rejected by the FDA. The Manufacturers are wrong on both counts. Their arguments rest on a mischaracterization of both Plaintiffs' claims and the controlling jurisprudence concerning federal preemption of state law claims involving prescription drugs regulated by the FDA.

Nothing about the nature of Plaintiffs' claims has changed since the Court denied the Manufacturers' motion to dismiss. Just as the Court concluded then, the Manufacturers have failed to carry their burden to show that Plaintiffs' claims based on the Manufacturers' false and misleading marketing of opioid medications are preempted. Report & Recommendation, Doc. 1025, PageID # 24856; Opinion & Order, Doc. 1203, PageID # 29021 (adopting the R&R with respect to preemption).

A. Plaintiffs' claims are based on the Manufacturers' false and misleading promotion, and do not conflict with FDA-approved labeling and marketing for opioid medications.

Plaintiffs do not dispute that the FDA approved the Manufacturers' opioid medications. As the Court noted when denying the Manufacturers' motion to dismiss, Plaintiffs' claims are not based on the mere fact that the Manufacturers marketed and sold opioid medications, but rather on the fact that the Manufacturers falsely and misleadingly promoted the use of opioid medications by deliberately overstating their claimed benefits while downplaying the risks associated with their use. *Id.* at PageID 24855.

The Manufacturers argue that Plaintiffs seek to hold them liable for marketing opioid medications for the treatment of chronic, non-cancer pain, and for not including dose or duration limitations or warnings on the label. The Plaintiffs' Third Amended Complaint identifies nine categories of misrepresentations made by the Manufacturers. *See, e.g.,* Third Amended Complaint (Doc. 1466) ¶ 172. None of these misrepresentations includes the claim that opioids cannot be safe and effective for the long-term treatment of chronic non-cancer pain. Thus, the Manufacturers cannot point to any allegation in Plaintiffs' marketing claims that directly conflicts with any FDA determination about the safety or effectiveness of opioid drugs.

Plaintiffs do not challenge the FDA-approved labeling of any of the Manufacturers' products, but rather their false and misleading promotion of those drugs. There can be no preemptive conflict

between those state law claims and federal law, because federal law did not *require* the Manufacturers to promote their products—let alone to promote them misleadingly, through falsehoods and omissions. They were not required to disseminate falsehoods about the likelihood, frequency, and seriousness of addiction, or engage in any of the other deceptive marketing described in the Third Amended Complaint. *Cf. In re Opioid Litigation*, 2018 WL 3115102 (N.Y. Sup. Ct., June 18, 2018) (New York court found no preemption because "manufacturer defendants have failed to show that the FDA has approved their means, methods, and/or content of their drug promotion"); *State v. Purdue Pharma. L.P.*, No. 17-2-25505-0, slip op. at 2 (attached as Exhibit 1) (Washington court "finds that the State has alleged that Purdue engaged in conduct that exceeded the parameters of the FDA labeling"). Moreover, the allegations in Plaintiffs' Third Amended Complaint do not require Manufacturer Defendants to stop selling their products, only to hold them responsible for marketing them deceptively.

Because drug manufacturers are under no federal obligation to promote their products, courts have consistently refused to find preemption of fraud-based marketing claims involving FDA-approved drugs. This is true even where the manufacturer would be precluded from altering its label, as in the case of generic drugs for which the manufacturer is required to maintain a label identical to the branded equivalent. *See Arters v. Sandoz Inc.*, 921 F. Supp. 2d 813, 819-820 (S.D. Ohio 2013) (state law fraud claims based on defendants' allegedly fraudulent or unreasonably dangerous promotion of generic drug were not preempted); *Priest v. Sandoz, Inc.*, No. A-15-CV-00822-LY-ML, 2016 WL 11162903, at *7 (W.D. Tex. Dec. 29, 2016), report and recommendation adopted, No. 1:15-CV-822-LY, 2017 WL 8896188 (W.D. Tex. Jan. 31, 2017) (claims based on fraudulent promotion not preempted because "nothing in the FDCA requires defendants to promote their drug for an off-label use"); *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, 2016 WL 861213, at *3 (N.D. Ill. Mar. 7, 2016) (obligation to refrain from falsely promoting drugs does not

make it impossible to comply with federal law regarding labelling); *Beavers-Gabriel v. Medtronic, Inc.*, No. CIV. 13-00686 JMS, 2015 WL 143944, at *6 (D. Haw. Jan. 9, 2015) (no impossibility preemption for fraud claims); *Elmore v. Gorsky*, No. 2:12-CV-00347, 2012 WL 6569760, at *3 (S.D. Tex. Dec. 17, 2012).

The Manufacturers cite to numerous expert reports and depositions that, they suggest, show Plaintiffs' claims are different from what has been pleaded. (Mot. p. 6-7). But again, the Manufacturers miss the point. The cited excerpts do not change the nature of Plaintiffs' *claims*, but rather merely constitute *evidence* that the Manufacturers engaged in false and misleading promotion of their opioid medications.[5]

Plaintiffs' claims do not interfere with the role played by the FDA in the approval and regulation of opioid medications. They merely seek to impose state-law duties not to promote those drugs using false and misleading claims that go far beyond the representations approved by the FDA in the labeling. Plaintiffs' claims are not preempted.

B. Plaintiffs are not asserting claims based on opioid medication labeling, and the Manufacturers cannot prove by "clear evidence" that the fraudulent marketing representations they made were required by the FDA.

The Manufacturers have attempted to convert Plaintiffs' fraudulent marketing claims into "failure to warn" claims under *Wyeth v. Levine*, 555 U.S. 555 (2009), and *Merck Sharpe & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019), in order to manufacture a preemption defense where none exists. But as noted above, Plaintiffs are not asserting claims based on any alleged deficiencies in the FDA-approved labeling for the Manufacturers' opioid medications. Rather, Plaintiffs' claims are based on

[5] This is yet another example of the Manufacturers attempting to create a preemption defense where none exists. Plaintiffs' claims are defined by their pleadings, not by what is stated in an expert report. If the Manufacturers take issue with any opinions stated in Plaintiffs' expert reports, they can seek to limit or exclude those by a *Daubert* motion or a motion in limine. The fraudulent marketing claims Plaintiffs have advanced—all of which are supported by substantial evidence, as set forth in Plaintiffs' responses to other motions—challenge only fraudulent marketing statements that go beyond the labeling and which the FDA has not approved.

the Manufacturers' false and misleading promotion of their drugs to physicians and the medical community. For this simple reason, the Manufacturers' preemption argument fails on its face.

Moreover, the Manufacturers have failed to show that Plaintiffs' fraudulent marketing claims conflict in any way with the regulatory actions taken by the FDA. The Manufacturers first rely on a 2013 FDA partial denial of a citizen petition (the "PROP petition") regarding the risks associated with long-term use of opioid medications for non-cancer pain. (Exhibit 12 to the Manufacturers' Motion). The Manufacturers are wrong for several reasons. First, the FDA did not reject, or even consider, the specific fraudulent representations upon which Plaintiffs' claims are based. *In re Opioid Litigation*, 2018 WL 3115102, *8 (N.Y. Sup. Ct., June 18, 2018) ("the plaintiffs' allegations here are not based upon the same theories and scientific evidence presented in the PROP petition.") Second, the Manufacturers fail to note that the FDA required manufacturers to *strengthen* their opioid medication warnings in response to the PROP petition: (1) they were required to include in the "boxed warning" section of the label that extended-release, long-acting (ER/LA) opioids "expose patients and other users to the risks of opioid addiction, abuse, and misuse which can lead to overdose and death; and (2) the Indications and Usage section of the label was modified to instruct prescribers that ER/LA opioid medications "should be used only when alternative treatments are inadequate because of the serious risks of these drugs." Ex. 12, p. 7 (emphasis in original). Finally, with respect to the use of opioids for chronic pain, Plaintiff's claims do not turn on the contention that the Manufacturers should not have marketed their opioids products for non-cancer chronic pain. Rather, Plaintiffs allege that the Manufacturers were precluded from using falsehoods and misrepresentations in their marketing. No label change was required for the Manufacturers to stop using fraudulent misrepresentations in connection with marketing opioids for their approved uses, including for chronic pain, nor are Plaintiffs' claims concerning the fraudulence of particular marketing messages inconsistent with labeling determinations made by the FDA in response to the PROP petition. For these reasons, the

FDA's decision not to distinguish between cancer and non-cancer chronic pain in connection with the PROP petition has nothing to do with the claims asserted in this case.

In addition, the age of the 2013 PROP decision undermines its relevance in evaluating whether the FDA would have rejected a label change more recently. As the Seventh Circuit noted in *Mason v. SmithKline Beecham Corp.*, "we do not find the FDA's rejection of the citizen petitions or its call to do more research very compelling for either side. Even the latest of these findings was made several years before Tricia's suicide. This temporal gap is especially important in the analysis of prescription drugs because it constantly evolves as new data emerges." 596 F.3d 387, 394-95 (7th Cir. 2010) (reversing preemption summary judgment because manufacturer failed to demonstrate by clear evidence that the FDA would have rejected a proposed label change).[6]

The Manufacturers also cite a May 2019 "memorandum" discussing opioid medications as "clear evidence" that the FDA would not approve opioid label changes. (Mot. p. 13, and Def. Ex. 1). The memorandum was included in an "FDA Briefing Document" prepared for the Joint Meeting of the Drug Safety and Risk Management (DSaRM) Advisory Committee and Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC). The briefing document makes the following observations:

- "The attached package contains background information prepared by the Food and Drug Administration (FDA) for the panel members of the advisory committee. The FDA background package often contains assessments and/or conclusions and recommendations written by individual FDA reviewers. Such conclusions and recommendations do not necessarily represent the final position of the individual reviewers, nor do they necessarily represent the final position of the Review Division or Office." (*See* Def. Ex. 1, p. 2)

[6] *See also In re Testosterone Replacement Therapy Products Liability Litigation Coordinated Pretrial Proceedings*, 2017 WL 1836435 *10 (N.D. Ill. May 8, 2017). That court rejected a preemption claim that was based on the denial of a citizen petition, noting that the FDA might have many reasons for denying such a petition while a similar proposal from the manufacturer might be viewed differently. The court further noted, "[a]nd irrespective of the rationale for the FDA's determination, its rejection of the warnings is not 'clear cut," because the agency itself indicated the possibility of future action." *Id.* The FDA's response to the PROP petition reflects a similar "possibility of future action" that, as described below, is reinforced by FDA's most recent action on opioid medications in June of 2019.

- "We have brought the clinical utility and safety concerns associated with the higher range of opioid analgesic dosing (both in terms of higher strength products and higher daily doses) in the outpatient setting, to this Advisory Committee in order to gain the Committee's insights and opinions, and the background package may not include all issues relevant to the final regulatory recommendation and instead is intended to focus on issues identified by the Agency for discussion by the advisory committee." (*Id.*)

- "The FDA will not issue a final determination on the issues at hand until input from the advisory committee process has been considered and all reviews have been finalized. The final determination may be affected by issues not discussed at the advisory committee meeting." (*Id.*)

The FDA Briefing Document notes on its face that it is preliminary in nature and does not represent the final position of the FDA. As such it does not have preemptive effect. As the Supreme Court noted in *Albrecht*,

> [T]he only agency actions that can determine the answer to the pre-emption question, of course, are agency actions taken pursuant to the FDA's congressionally delegated authority. The Supremacy Clause grants "supreme" status only to the "the Laws of the United States." … Federal law permits the FDA to communicate its disapproval of a warning by means of notice-and-comment rulemaking setting forth labeling standards; by formally rejecting a warning label that would have been adequate under state law; or with other agency action carrying the force of law.

Albrecht, 139 S. Ct. at 1679. Justice Thomas expanded on this point in his concurring opinion: "neither agency musings nor hypothetical future rejections constitute pre-emptive 'Laws' under the Supremacy Clause." 139 S. Ct. at 1682.

The briefing document does not prove – by clear evidence or otherwise – that the FDA would reject opioid labeling changes. Instead, it shows that the FDA is deeply concerned about the opioid crisis and is evaluating whether label changes or other regulatory actions are appropriate. It also is irrelevant to Plaintiffs' claims that the Manufacturers illegally promoted their opioid medications using false and misleading information. Consequently, the Manufacturers have failed to carry their burden under *Levine* and *Albrecht* of demonstrating by "clear evidence" that the FDA would reject changes to opioid labeling, so their preemption argument fails.

The Manufacturers cite a recent North Dakota federal district decision in support of their preemption argument. (*See* Mot. p. 12). Plaintiffs respectfully submit that the North Dakota decision was incorrectly decided. It directly conflicts with the Special Master's Report and Recommendations in this case, which were adopted by this Court. (Doc. 1025, preemption findings adopted in Doc. 1203). It also conflicts with decisions in related cases where courts have rejected preemption arguments similar, if not identical, to those asserted by the Manufacturers in this case. *See, e.g., In re Opioid Litigation*, 2018 WL 3115102 *9 (N.Y. Sup. Ct., June 18, 2018) ("the court concludes that, under the circumstances, the FDA's 'less-than-definitive determination' concerning PROP's request for maximum dosage and treatment duration does not meet the Wyeth standard of clear evidence."); *State v. Purdue Pharma. L.P.*, No. 17-2-25505-0, slip op. at 2 (Exhibit 3).[7]

C. Plaintiffs' claims are not based on alleged "fraud on the DEA," but rather on the Manufacturers' false and misleading promotion of their opioid medications.

As with their arguments regarding Plaintiffs' marketing claims, the Manufacturers again either fail to understand Plaintiffs' state law claims that implicate the federal Controlled Substances Act, or they are deliberately attempting to mislead the Court.

Like the other defendants in the preemption motions discussed above, the Manufacturers rely on *Buckman*, but *Buckman* does not apply to Plaintiffs' fraudulent marketing claims in this case. As discussed above, the claims at issue in *Buckman* were not asserted against the manufacturer of the orthopaedic bone screws at issue in the case, but against a *consulting firm* that had assisted the manufacturer in obtaining FDA approval. *Buckman*, 531 U.S. at 343. Unlike the orthopaedic bone screw manufacturer, the consulting firm owed no duties to the plaintiffs. The Supreme Court held

[7] The North Dakota court held that the defendant satisfied the *Levine/Albrecht* "clear evidence" standard. *State ex rel. Stenehjem v. Purdue Pharma L.P.*, 2019 WL 2245743, *5-7 (Dist. N.D., May 10, 2019). However, the 2019 FDA Briefing Document cited by the Manufacturers, dated a few days after the North Dakota court's decision, seriously undermines that decision. Not only is there no "clear evidence" that the FDA would reject a label change; there is clear evidence that the FDA is actually considering that very issue.

that the fraud claims against the consulting firm "exist[ed] solely by virtue of the" federal law that required disclosure of information to the FDA during the approval process; as a result, those claims sought to police fraud against a federal agency and were preempted. *Id.* at 347-348, 352-353.

The Plaintiffs in this case assert claims based on state law duties not to misrepresent the safety and efficacy of their opioid medications or commit fraud in promoting their use. Plaintiffs' claims against the Manufacturers do not depend upon the DEA's decision to increase quotas for opioid medications; rather, those increased quotas were indicative of the effectiveness of the Manufacturers' (and others') ability to induce healthcare professionals to prescribe their opioid medications in ever-increasing numbers. Plaintiffs' claims are based on the Manufacturers' fraudulent and misleading promotion directed toward healthcare providers, which drove the massive increase in prescriptions, and (as with the Pharmacy/Distributor and Small Distributor Defendants) the Manufacturers' failure to exercise reasonable care in connection with their manufacturing, advertising, marketing, selling, and distributing opioids. These common law duties arise by virtue of state law, and are not predicated solely on the CSA or any increase in opioid manufacturing quotas authorized by the DEA. The increased DEA quotas resulted from the Manufacturers' and others' conduct, but do not in and of themselves form the basis of Plaintiffs' claims.

Because Plaintiffs' claims against the Manufacturers are based on their false and misleading marketing of opioid medications rather than "fraud on the DEA," Plaintiffs' claims are not preempted under *Buckman*.

D. Since Plaintiffs' state law claims are not preempted, their RICO claims are likewise not precluded.

The Manufacturers' argument for preclusion of Plaintiffs' RICO claims is predicated on their assertion that Plaintiffs' state law claims are preempted. (*See* Mot. p. 14). But since those claims are not preempted for the reasons discussed above, Plaintiffs' RICO claims likewise are not precluded.

IV. CONCLUSION

For the reasons stated, the Court should deny the following motions in their entirety: (1) Motion for Summary Judgment on Preemption by Pharmacy Defendants, ABDC, Cardinal, and McKesson (Dkt. 1772); (2) The Non-RICO Small Distributors' Motion for Partial Summary Judgment on Plaintiffs' "Failure to Report" and "Fraud on the DEA" Claims (Dkt. 1754); and (3) Manufacturer Defendants' Motion for Summary Judgment that Plaintiffs' State-Law Claims are Preempted and their Federal Claims are Precluded (Dkt. 1760).

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Respectfully submitted,

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